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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/816,655	03/26/2001	Ryuji Ueno	Q58513	5746

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SUGHRUE, MION, ZINN, MACPEAK & SEAS, PLLC
2100 PENNSYLVANIA AVENUE, N. W.
WASHINGTON, DC 20037-3213

EXAMINER
FAY, ZOHREH A

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 02/27/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/816,655	Ueno et al.
Examiner	**Art Unit**
Zohreh Fay	1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☐ Responsive to communication(s) filed on _____.

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1-18 is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 1-18 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 5

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☐ Other:

Claims 1-18 are presented for examination.

Claims 1-18 are rejected under 35U.S.C. 112 first paragraph, because the specification while being enabling for certain disease or condition associated with apoptosis, does not reasonably provide enablement for the broad phrase of "a disease or condition associated with apoptosis. The specification does not enable any person skilled in the art to which it pertains or with which it is most nearly connected to make or use the reinvention commensurate in scope with these claims. The instant specification fails to provide information that would allow the skilled artisan o practice the instant invention without undue experimentation. Attention is directed to Inre wands, 8 USPQ 1400 (CAFÉ 1988) at 1404 where the court set forth eight factor to consider when assessing if a disclosure would have required undue experimentation. Citing Exparle foreman, 230 USPQ 546 (Bdapls1986) at 547 the court recited eight factors:

1) The quantity of experimentation necessary
2) The amount of direction or guidance provided,
3) The presence or absence of working examples,
4) The nature of the invention,
5) The state of the art,
6) The relative skill of those in the art,
7) The predictability of the art.
8) The breath of the claims

Applicant fails to set forth the criteria that defines" a disease or condition associated with apoptosis." Additionally applicant fails to provide information allowing the skilled artisan to ascertain these conditions without undue experimentation. The pharmaceutical art is unpredictable requiring each embodiment to be individually assessed for physiological activity. The instant claims read on all "conditions associated with apoptosis" necessitating an exhaustive search for embodiment suitable to practice the claimed invention.

Applicant fails to provide the claimed invention absence undue experimentation.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any

evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Aoyama-Hyashi etal

Ayoma-Hyashi etal teach the use of prostaglandin E for the inhibition of apotosis. See the entire abstract; the above reference differs from the claimed invention in the presence of the claimed specific prostaglandin E. One skilled in the art would have been motivated to employ the teachings of the above reference, since it relates to the use of prostaglandin's E. in general for the treatment of apoptosis. To use a specific derivative of prostaglandin's E. does not create a patentably distinct use in the absence of evidence to the contrary. The above reference makes clear that the prostaglandin E. has been previously used for the inhibition of apoptosis.

There is no comparative data to show the advantages of the claimed prostaglandin E. over the prostaglandin E. used by the prior art. Applicant has presented no evidence to establish the unexpected or unobvious nature of the claimed invention, and as such claims 1-18 are properly rejected under 35 U.S.C. 103.

Fay/dl

January 30,2002

SUBASH FAY
PRIMARY EXAMINER
GROUP 1200